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Food Safety And Inspection Service
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AUDIT REPORT FOR IRELAND
JULY 16 THROUGH AUGUST 1, 2002

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Ireland's meat inspection system from July 16 through August 1, 2002. Five establishments certified to export meat to the United States were audited. Four of these were slaughter establishments; the other was conducting processing operations.

The last audit of the Ireland meat inspection system was conducted in November 2001. Four establishments were audited. The auditor found serious deficiencies in two establishments. One was designated as marginal/re-review, and the other establishment was unacceptable. The following major concerns were reported at that time:

1. Insanitary storage of product was found in two of the four establishments.

2. Hand-washing facilities were inadequate in one establishment.

3. None of the slaughter establishment management officials had developed a statistical process control procedure to evaluate the results of the generic *E. coli* testing.

4. Turnaround times in some sections of the three residue testing laboratories did not meet FSIS expectations.

5. The intra-laboratory check sample programs in the residue testing laboratories did not meet FSIS requirements.

The importation of meat products of beef origin from Ireland was not allowed at the time of this audit due to presence of Bovine Spongiform Encephalopathy.

From January through June 30, 2002, Ireland establishments exported 2,503,664 pounds of pork product to the U.S. Port-of-entry (POE) rejections totaled 966 pounds for transportation damage and missing shipping marks.

PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with Irish national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second was conducted by on-site visits to establishments. The third was a visit to three government laboratories performing analytical testing of field samples for the national residue testing program, and a private culturing field samples for the presence of microbiological contamination with *Salmonella* and generic *E. coli*.

Ireland's program effectiveness was assessed by evaluating five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials (this was the case with one establishment—see below).

RESULTS AND DISCUSSION

Summary

Effective inspection system controls were found to be in place in four of the five establishments audited; four establishments (Ests. 293, 332, 355, and 738) were recommended for 30-day reassessment. One establishment (Est. 300) was found to be unacceptable. Details of audit findings, including compliance with HACCP, SSOPs, and testing programs for *Salmonella* and generic *E. coli*, are discussed later in this report.

As stated above, five major concerns had been identified during the last audit of the Irish meat inspection system, conducted in November 2001:

1. Insanitary storage of product was found in two of the four establishments.

2. Hand-washing facilities were inadequate in one establishment.

3. None of the slaughter establishment management officials had developed a statistical process control procedure to evaluate the results of the generic *E. coli* testing.

4. Turnaround times in some sections of the three residue testing laboratories did not meet FSIS expectations.

5. The intra-laboratory check sample programs in the residue testing laboratories did not meet FSIS requirements.

During this new audit, the auditor determined that the concerns had been addressed and corrected except as noted below. The following deficiencies were cause for major concern during this new audit:

1. The SSOP pre-operational and operational sanitation documents did not accurately reflect the conditions observed in the establishments.

2. The HACCP documentation was found to be incomplete in varying degrees, on verification, corrective action and the pre-shipment review.

3. One of the slaughter establishments had not developed a statistical process control procedure to evaluate the results of the generic *E. coli* testing. This was a repeat finding.

4. Turnaround times in two sections of the two residue testing laboratories did not meet FSIS expectations. This was a repeat finding.

5. The intra-laboratory check sample programs in the residue testing laboratories did not meet FSIS requirements. This was a repeat finding.

6. Pieces of foreign material (feces and rail dust) were observed on carcasses after the final rail inspection in the slaughter room; foreign material (feces and grease) was observed on carcasses in the first cooler, and grease and rail dust were observed on carcasses in the second cooler in one establishment. These deficiencies were corrected by establishment officials.

Entrance Meeting

On July 16, 2002, an entrance meeting was held in the Dublin offices of the Department of Agriculture, Food & Rural Development (DAFRD), and was attended by Mr. Paddy Rogan, Deputy Chief Veterinary Officer, Department of Agriculture and Food (DAF); Mr. Frank Kenny, Senior Superintending Veterinary Inspector, DAF; Mr. Kilian Unger, Superintending Veterinary Inspector, DAF; Dr. Liam Regan, Chemist, State Laboratory; Dr. Monserrat Guterriez, Veterinary Inspector, Central Meat Control Laboratory, DAF; Dr. Dan O'Sullivan, Agricultural Inspector, Pesticide Control Laboratory, DAF; Ms. Catherine Murray, Executive Officer, DAF; and Mr. Martin Freeman, Higher Executive Officer (Pigmeat, Poultry & Eggs), DAF. FSIS was represented by Mr. Michael Hanley, Agricultural Attaché, American Embassy Dublin; and Dr. Oto Urban, International Audit Staff Officer. Topics of discussion included the following:

1. The auditor explained that the purpose of the audit was to establish whether the inspection system controls ensure that products eligible to enter the United States were produced either in compliance with the applicable European Commission (EC) Directives, or FSIS requirements in areas where EC Directives did not apply (SSOP and PR/HACCP programs). The three EC Directives that had been agreed to in the Veterinary Agreement as equivalent between EC and FSIS were:

    - Council Directive 64/433/EEC on health problems affecting intra-Community trade in fresh meat,
    - Council Directive 96/22/EEC on prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action,
    - Council Directive 96/23/EEC on measures to monitor certain substances and residues thereof in live animals and animal products.

2. The final travel arrangements and accommodations were discussed.

3. The Irish meat inspection officials were informed of the timeline for the country audit report: a draft of the report would be provided to them within 60 days of the exit meeting in Dublin; Ireland would have another 60 days to review the contents and provide comments to FSIS; and FSIS would consider any comments before issuing the final report.

4. The auditor discussed the data-collection instruments (SSOP and PR/HACCP) that would be used in the audits of the individual establishments (Attachments A, B, C, and D).

5. Information was provided to update the FSIS country profile for Ireland.

Headquarters Audit

There had been no changes in the organizational structure or upper levels of inspection staffing since the last U.S. audit of Irish's inspection system in November 2001, except that the position of the Chief Veterinary Officer was vacant at the time of the audit.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications. The FSIS auditor (hereinafter called "the auditor") observed and evaluated the process.

The auditor did not conduct a review of inspection system documents pertaining to the establishments listed for records review at the headquarters but at the inspection service office in establishments. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.

- Supervisory visits to establishments that were certified to export to the U.S.
- Label approval records such as generic labels, and animal raising claims.
- Sampling and laboratory analyses for residues.
- Pathogen reduction and other food safety initiatives such as SSOPs, HACCP programs, generic *E. coli* testing and *Salmonella* testing.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of products from livestock with conditions such as tuberculosis, cysticercosis, etc., and of inedible and condemned materials.
- Export product inspection and control including export certificates.
- Enforcement records, including examples of criminal prosecution, consumer complaints, recalls, seizure and control of noncompliant product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

The following concerns arose as a result the examination of these documents:

1. The SSOP pre-operational and operational sanitation documents did not accurately reflect the conditions observed in the establishments.

2. The HACCP documentation was found to be incomplete, in varying degrees, on verification, corrective action and the pre-shipment review.

Government Oversight

All inspection veterinarians and inspectors in establishments certified by Ireland's meat inspection system as eligible to export meat products to the United States were full-time DAFRD employees, receiving no remuneration from either industry or establishment personnel.

In Ireland, the central competent authority in relation to controls on production of pork and pork products is the Department of Agriculture and Food. The management structure of the Department under the Secretary General comprises nine Assistant Secretaries, the Chief Veterinary Officer (CVO) and the Chief Agricultural Inspector. The CVO is assisted by three Deputy Chief Veterinary Officers (DCVO) one of whom is responsible for matters relating to veterinary public health.

The Food Safety Authority of Ireland has legal responsibility under Irish law for the enforcement of all food safety legislation in Ireland and discharges that responsibility by having Service Contracts with the agencies (including the Department of Agriculture and Food) that carry out the enforcement activities.

Establishment Audits

Five establishments (Ests. 293, 300, 332, 355, and 738) were certified to export meat products to the United States at the time this audit was conducted; all were visited for on-site audits. In four of the five establishments visited, both DAFRD inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products. One establishment (Est. 300) was found by the DAFRD officials leading the audit to fail to meet basic U.S. requirements and was removed by them from the list of establishments eligible to export meat products to the United States.

Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information was also collected about the risk areas of government oversight of accredited, approved, and private laboratories; *intra*-laboratory quality assurance procedures, including sample handling; and methodology.

The Central Meat Control Laboratory and The Pesticides Laboratory in Dublin were audited on July 24, 2002. Except as noted below, effective controls were in place for sample handling and frequency, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions. The methods used for the analyses were acceptable. No compositing of samples was done (this was not a deficiency). The following deficiencies were observed:

1. The check sample program did not meet FSIS requirements. The check sample for chloramphenicol was prepared by the analyst and not by his/her supervisor. This was going to be corrected by the laboratory officials.

2. Turnaround times for pesticides and arsenic in two sections of the two residue-testing laboratories did not meet FSIS expectations. This was a repeat finding.

Ireland's microbiological testing for *Salmonella* was being performed in private laboratories. One of these, the Independent Microlabs in Portlaoise, Co. Laois, was audited. The auditor determined that the system met the criteria established for the use of private laboratories under FSIS's Pathogen Reduction/HACCP rule. These criteria are:

1. The laboratories have been approved by the government, accredited by third party accrediting organization with oversight by the government, or a government contract laboratory.
2. The laboratories have properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and record-keeping capabilities.
3. Results of analyses are being reported to the government or simultaneously to the government and establishment.

Effective controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices, an intra-laboratory check sample program, and a written corrective action program.

Establishment Operations by Establishment Number

The following operations were being conducted in the five establishments:

Beef slaughter, boning, processing, and freezer/cold store - one establishment (300)
Pork slaughter, boning and, freezing/cold store – one establishment (332)
Pork slaughter, boning, processing, and freezing/cold store – two establishments (293, and 355)
Pork processing and freezing/cold store – one establishment (738)

SANITATION CONTROLS

Based on the on-site audits of establishments, Ireland's inspection system had controls in place for light, ventilation, plumbing and sewage, water supply, and dressing rooms/ lavatories.

Sanitation Standard Operating Procedures (SSOP)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOP was found to meet the basic FSIS regulatory requirements with the following variations:

1. Dried meat scraps were observed on the ceiling in the boning room (Est. 355). This deficiency was not reported in the daily pre-operational sanitation record. After this deficiency had been pointed out, the establishment took immediate corrective action.

2. Pieces of meat scraps and fat were observed on the overhead structures and in metal bins in the boning area (Est. 293). These deficiencies were not recorded on pre-operational and operational sanitation records. The metal bins were cleaned immediately. However, no corrective action was observed on the cleaning of the overhead structures.

3. Grease from the overhead structures was observed on several carcasses in the boning room. This deficiency was corrected by the establishment management (Est. 293).

4. Over-product condensation was observed in the processing/formulation room, and dripping condensation was observed in close proximity to carcasses in the cooler (Est. 293). The establishment management corrected this deficiency.

5. Pieces of dried meat and fat were observed on the overhead structures and equipment during the pre-operational sanitation in the boning room (Est. 332). This deficiency was corrected immediately by the establishment management.

6. Condensation was observed over product (carcasses) and over a product passageway (door) in the second cooler (Est. 300). The establishment officials corrected this deficiency.

7. The SSOP record had conflicting information regarding a documented deficiency and the preventive action was not present (Est. 300). The establishment management scheduled this deficiency for correction.

8. Dried meat and fat from previous days' operations was observed on the ceiling of the filling/processing room (Est. 738). The pre-operational and operational sanitation records did not reflect the conditions observed in the processing areas. The establishment management promised improvement in this area.

Establishment Grounds and Pest Control

1. Flies were observed in the dressing room and in the container washing area (Est. 355). Establishment officials assured more active involvement in the insect control program.

2. Flies were observed in the dressing room and an opening to the outside premises was observed in the shipping room (Est. 293). These deficiencies were scheduled for correction by the establishment management.

3. Spider webs were observed in the box storage room (Est. 332). This deficiency was corrected immediately by the establishment management.

4. Insectocutors were placed over edible product and an edible product trafficway (Est. 300). This was scheduled for correction by the establishment.

5. The doors connecting with the outside premises were not properly closed due to being damaged. Thus, there was a potential for the entrance of pests in the receiving area and the packaging room (Est. 738). The establishment had documented a pest problem in the months of the summer and fall. This was scheduled for correction by the establishment management.

Establishment Construction/Maintenance

1. Doors were not properly closed in the shipping area, creating a possibility of pest entrance to the establishment (Est. 355). This deficiency was corrected immediately by the establishment management.

2. Rusty equipment and chains were observed in the boning room (Est. 332). The establishment officials scheduled this deficiency for correction.

3. Water was dripping from a refrigeration unit in close proximity to carcasses in the first cooler, and water was dripping in close proximity to the edible product conveyor belt in the viscera chiller (Est. 300). The establishment management corrected these deficiencies.

4. Damaged boxes and ice falling on boxes were observed in the cold storage (Est. 300). The first deficiency was corrected by the establishment management, and the second deficiency was scheduled for correction.

5. Rusty cages were stored in the freezer and were also stored on the outside premises (Est. 300). This was scheduled for correction by the establishment.

6. Condensation was dripping onto two of the stored boxes causing moisture damage to the boxes in the dispatch chill room (Est. 738). Corrective action was performed immediately by the establishment management.

Establishment and Utensils

1. Containers used for edible product in the boning room were not properly washed (Est. 355). The establishment immediately corrected this deficiency.

2. Dirty trays that were considered to be clean were observed in the offal room and containers assigned for edible product use were used for inedible product (Est. 293). The establishment management corrected these deficiencies.

3. Trays used for edible product were used for inedible product and there was no separation of clean and dirty equipment in the packaging room (Est. 300). The first deficiency was corrected and the second was scheduled for correction by the establishment management.

4. Dirty trays and other equipment parts were observed in the washing room after washing and in the filling/processing room (Est. 738). This deficiency was corrected immediately by the establishment management.

Sanitary Operations

1. The temperature of the sanitizer was below required temperature (82°C) in the slaughter room (Est. 293). This deficiency was corrected immediately by the establishment officials.

2. The door separating the shipping room with the outside premises was not properly closed, probably due to being damaged. Thus, there was a space between the floor and bottom of the door creating a possible entrance for pests (Est. 332). This deficiency was scheduled for correction by the establishment management.

3. Two different employees placed trays used for edible product directly on the floor (Est. 332). This deficiency was corrected immediately by the establishment officials.

4. The air pipe of the carcass split saw was contacting inedible product below the employee stand and then carcasses in the slaughter room and several carcasses were observed contacting the wall in the first cooler (Est. 300). The first deficiency was corrected immediately by the establishment officials, while the other deficiency was not observed to be corrected by the auditor.

5. One of the sanitizers was observed to have the water temperature below the required level (82°C) and two employees did not have their street clothes properly covered by their working clothes in the boning room (Est. 300). Both deficiencies were corrected by the establishment management.

6. Plastic strip curtains were contacting the floor creating a potential to contaminate exposed product in the tempering chiller (Est. 738). This was scheduled for correction by the company management.

Thirty-day notices of reassessment were given to establishments 293, 332, 335, and 738 for SSOP and/or sanitation deficiencies.

ANIMAL DISEASE CONTROLS

With the exceptions listed below, Ireland's inspection system had controls in place to ensure adequate animal identification, post-mortem inspection procedures and dispositions, condemned and restricted product control, and procedures for sanitary handling of returned and rework product.

1. Improper ante-mortem inspection of received pigs was observed in Ests. 355 and 332. The incoming animals were observed from one side only by the inspection service. The inspection service officials corrected this deficiency.

2. Drainage of pens for suspect animals was not directed away from other pens (Ests. 293 and 332). This deficiency was scheduled for correction by establishment officials.

There were reported to have been no outbreaks of animal diseases with public-health significance since the previous U.S. audit

RESIDUE CONTROLS

Ireland's National Residue Testing Plan for 2002 was being followed and on schedule. The Ireland inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals.

SLAUGHTER/PROCESSING CONTROLS

The Irish inspection system had controls in place to ensure adequate humane handling and slaughter, ingredient identification, control of restricted ingredients, formulations, packaging materials, laboratory confirmation, label approvals, inspector monitoring, processing records, post-processing handling, processing defect actions by establishment personnel, and processing control by inspection personnel.

HACCP Implementation

All establishments approved to export meat products to the United States are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

The HACCP programs were found to meet the basic FSIS regulatory requirements except for the following:

1. The HACCP plan verification program did not include all required points (Ests. 355, 293, and 300). This was scheduled for correction by the establishment management.

2. The HACCP plan corrective action did not include all required points (Ests. 355, 293, and 300). This deficiency was scheduled for correction by the establishment officials.

3(a) The HACCP plant pre-shipment review was not written but it was performed under different QA program (Ests. 355, 293, 332, and 738). This is going to be corrected by the establishment.

(b) The HACCP plan CCPs included ante-mortem inspection and post-mortem (head) inspection (Est. 300). The Critical Limits (CL) included sign off for ante-mortem inspection, many of them were in a range rather than a specific limit, and one CCP had no CL at all. The pre-shipment review was not written and performed by the establishment. The establishment official could not promise correction of these CCPs as they are the responsibility of the inspection service.

A "30-day" notice of reassessment given to Establishment 335 for HACCP deficiencies.

Testing for Generic *E. coli*

Ireland had adopted the FSIS regulatory requirements for *E. coli* testing.

Four of the five establishments audited were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing, and were audited and evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

The *E. coli* testing programs were found to meet the basic FSIS regulatory requirements, with the following exception:

- One establishment (Est. 300) was sponging carcasses for the generic *E. coli* testing program and was supposed to assess results by using the statistical process control technique. However, an excising samples criteria was used by the establishment for sample testing. The inspection service is going to check on the correction of this deficiency.

Additionally, establishments had adequate controls in place to prevent meat products intended for Ireland domestic consumption from being commingled with products eligible for export to the United States.

ENFORCEMENT CONTROLS

Inspection System Controls

Except as noted below, and with the exception of the unacceptable establishment (Est. 300), the DAFRD inspection system controls [ante-and post-mortem inspection procedures and dispositions, control of restricted product and inspection samples, control and disposition of dead, dying, diseased or disabled animals, boneless meat reinspection, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, monitoring and verification of establishment programs and controls (including the taking and documentation of corrective actions under HACCP plans), inspection supervision and documentation, the importation of only eligible livestock from other countries (i.e., only from eligible countries and certified establishments within those countries), and the importation of only eligible meat products from other counties for further processing] were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources. The following deficiency was observed in this risk category:

- The official government stamp was not visible, or legible, on many carcasses in several places in Est. 300 (coolers, pre-boning and boning rooms). The in-plant and regional

veterinarians reported this deficiency several times but there was no corrective action taken.

Testing for *Salmonella* Species

Four establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

Ireland has adopted the FSIS regulatory requirements for *Salmonella* testing with exception of the following equivalent measures:

1. Program development: establishments certified to export meat to the United States develop their own *Salmonella* testing program and the program is approved by the Irish inspection service.

2. Sample collection: establishment personnel collect the samples, and Irish inspection service provides oversight and monitoring of the establishment's sampling procedures.

3. Laboratories: Ireland uses private laboratories for *Salmonella* testing, which are required to:

    - Have been accredited by Ireland,
    - Have suitable facilities and equipment, properly trained personnel, reporting and record-keeping capabilities, and a written quality assurance program,
    - Report test results directly to the Irish inspection service.

Ireland had adopted the FSIS performance standards for *Salmonella*. If performance standards were exceeded, the actions specified in the USDA rule would apply: at the first failure, measures would be taken to correct the problem, at the second, a review of the HACCP system would be undertaken and, at the third, inspection would be withdrawn.

Samples for *Salmonella* testing were delivered to the private lab the same day they were taken, and were either analyzed the same day they were received. Results were reported to both establishment and Inspection officials independently.

Species Verification Testing

At the time of this audit, Ireland was exempted from the species verification-testing requirement. Ireland has advised FSIS in writing that the following five conditions were being met:

1. Carcasses and products are transported between establishments in devices which are sealed with a tamper-detectable inspection seal by the Inspection Service at the

originating establishment and broken by the Inspection Service at the receiving establishment.
2. Brands and sealing devices used by the Inspection Service to identify and seal product are kept under Inspection Service security.
3. Establishments are under continuous Inspection Service supervision while operating. No operations may take place without Inspection Service supervision.
4. Only one species of livestock or meat is allowed in the slaughter or processing areas at one time.
5. Product must be exported to the United States in a cargo container sealed by the Inspection Service.

During the audit, the auditor verified that these conditions continued to be met.

Monthly Reviews

FSIS requires monthly supervisory visits to U.S.-listed establishments during any month when they are producing U.S.-eligible product. Six Regional Veterinary Officers, who headed the six Public Health Regions, were performing these reviews. They performed the initial periodic reviews, and reported directly to the Deputy Chief Veterinary Officer. There was also a headquarters level of review. All the internal reviewers were veterinarians with at least five years of experience in meat inspection, with authority of delisting establishments. The schedule of the internal reviews was arranged by the Regional Veterinary Officers, each of whom developed the program in his region.

The internal review program was not applied equally to both export and non-export establishments, however, slaughterhouses were visited by the local veterinary inspector on a daily basis. Internal review visits were usually not announced in advance. If announced, regional reviews get approximately 48 hours advanced notice, while headquarters reviews get 4-5 days advance notice. At least once monthly, internal reviews were conducted by the Regional Veterinary Officers. The records of audited establishments were kept in the inspection offices of the individual establishments. Copies were routinely maintained on file for a minimum of three years.

In the event that an establishment is found, during one of these internal reviews, to be out of compliance with U.S. requirements, and is delisted for U.S. export, before it may again qualify for eligibility to be reinstated, the inspection report is examined, then a corrective action program is formulated and both; announced and unannounced visits are performed by regional and headquarters reviewers, whose report will decide the reinstatement condition for the establishment in question.

Enforcement Activities

Irish meat inspection authorities demonstrated a very well developed enforcement program. Veterinary officers are authorized under the relevant legislation to enforce National measures

relating to animal health and welfare, including legislation concerning the control of animal disease, veterinary medicines, and the hygienic production of foods of animal origin, by routine inspection and sampling, by investigation and the acquisition of evidence, and by legal process in the courts, often in co-operation with the police and Custom officers. Veterinary Inspectors can, under national legislation, take appropriate enforcement actions in the case of non-compliances or breaches of the regulations. Non-compliances are categorized according to the risk to the consumer:

- Category 1 defects are those which constitute an immediate threat to public health. In these cases, the Veterinary Inspector may suspend production or prohibit the use of all or part of the plant or equipment until the risk has been eliminated.

- Category 2 defects are deemed to pose a potential threat to public health. In these cases, the Veterinary Inspector serves a notice requiring the owner or person in charge of the establishment to correct the defects within a specified time scale.

Exit Meetings

An exit meeting was conducted in Dublin on August 1, 2002. The Ireland participants were Mr. Paddy Rogan, Deputy Chief Veterinary Officer, Department of Agriculture and Food (DAF); Mr. Frank Kenny, Senior Superintending Veterinary Inspector, DAF; Mr. Kilian Unger, Superintending Veterinary Inspector, DAF; Mr. Paul Rafter, Superintending Veterinary Officer, Central Meat Control Laboratory, DAF; Dr. Monserrat Guterriez, Veterinary Inspector, Central Meat Control Laboratory, DAF; Ms. Catherine Murray, Executive Officer, DAF; Mr. Martin Freeman, Higher Executive Officer (Pigmeat, Poultry & Eggs), DAF; and Ms. Paula Barry Walsh, Superintending Veterinary Inspector, DAF. FSIS was represented by Mr. Michael Hanley, Agricultural Attaché, American Embassy Dublin; and Dr. Oto Urban, International Audit Staff Officer. The following topics were discussed:

1. The European Community Directive 64/433 that provides the basis for the criteria for the export approved establishment.

2. A copy of the delistment notice for the unacceptable establishment (Est. 300).

3. Notification of request four "30-day" notices. These were for: Est. 293 for SSOP deficiencies; Est. 332 for SSOP and sanitation deficiencies; Est. 335 for HACCP and sanitation deficiencies; and Est. 738 for SSOP and sanitation deficiencies.

4. Deficiencies observed during the establishment visits including product handling, product-contact equipment and surfaces, SSOP implementation, HACCP implementation, and generic *E. coli* testing.

5. Laboratory procedures including the check sample program not meeting FSIS requirements, and turnaround times for pesticides and arsenic not meeting FSIS expectations. This was a repeat finding.

CONCLUSION

The inspection system of Ireland was found to have effective controls to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments. Five establishments were audited: four were issued a 30-day re-assessment letter, and one was unacceptable. The deficiencies encountered during the on-site establishment audits, except in the establishment which was found to be unacceptable, were adequately addressed to the auditor's satisfaction.

Dr. Oto Urban (signed)*Dr. Oto Urban*
International Audit Staff Officer

ATTACHMENTS

A. Data collection instrument for SSOPs
B. Data collection instrument for HACCP programs
C. Data collection instrument for *E. coli* testing
D. Data collection instrument for *Salmonella* testing
E. Laboratory Audit Forms
F. Individual Foreign Establishment Audit Forms
G. Written Foreign Country's Response to the Draft Final Audit Report

Attachment A

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1.Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Fre-quency addressed	6. Respons-ible indiv. Identified	7. Docu-mentation done daily	8. Dated and signed
355	√	√	√	√	√	√	no	√
293	√	√	√	√	√	√	no	√
332	√	√	√	√	√	√	no	√
300	√	√	√	√	√	√	no	√
738	√	√	√	√	√	√	no	√

Attachment B

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment has conducted a hazard analysis that includes food safety hazards likely to occur.
3. The analysis includes the intended use of or the consumers of the finished product(s).
4. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
5. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
6. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
7. The plan describes corrective actions taken when a critical limit is exceeded.
8. The HACCP plan was validated using multiple monitoring results.
9. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
10. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
11. The HACCP plan is dated and signed by a responsible establishment official.
12. The establishment is performing routine pre-shipment document reviews.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Hazard analysis conducted	3. Use & users included	4. Plan for each hazard	5. CCPs for all hazards	6. Monitoring is specified	7. Corr. actions are described	8. Plan validated	9. Adequate verific. Procedures	10.Adequate documentation	11. Dated and signed	12.Pre-shipmt. doc. review
355	√	√	√	√	√	√	no	√	no	√	√	no
293	√	√	√	√	no	√	no	√	no	√	√	no
332	√	√	√	√	√	√	√	√	√	√	√	no
300	√	√	√	√	no	√	no	√	no	√	√	no
738	√	√	√	√	√	√	√	√	√	√	√	no

Data Collection Instrument for Generic *E. coli* Testing

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written procedure for testing for generic *E. coli.*
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is/are being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

Est. #	1.Written procedure	2. Sampler designated	3.Sampling location given	4. Predomin. species sampled	5. Sampling at the req'd freq.	6. Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
355	√	√	√	√	√	√	√	√	√	√
293	√	√	√	√	√	√	√	√	√	√
332	√	√	√	√	√	√	√	√	√	√
300	√	√	√	√	√	√	√	√	no	√

- One establishment (Est. 300) was sponging carcasses for the generic *E. coli* testing program and was suppose to have results by using the statistical process control technique. However, an excising sample criterion was used by the establishment for sample testing.

Data Collection Instrument for *Salmonella* testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. Salmonella testing is being done in this establishment.

2. Carcasses are being sampled.

3. Ground product is being sampled.

4. The samples are being taken randomly.

5. The proper carcass site(s) and/or collection of proper product (carcass or ground) are being used for sampling.

6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

Est. #	*1. Testing as required*	*2. Carcasses are sampled*	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
355	√	√	N/A	√	√	√
293	√	√	N/A	√	√	√
332	√	√	N/A	√	√	√
300	√	√	N/A	√	√	√